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November 30, 1999

Document Management Branch, (H.F.A. - 305)
Food and Drug Administration
5630 Fishers Lane, Room 106 1
Rockville, Maryland 20852

RE: Docket 97N - 4845

Dear Sirs:

I am writing to register my comments with regard to the proposed FDA regulation of allograft bone tissue for implantation.

Allograft bone has been used in many orthopedic procedures for a number of years. I believe it would impose a significant constraint on the ability of physicians to take care of patients, were this to come under regulatory scrutiny of the Food and Drug Administration, after so many years of being used in a safe manner. In particular, in my profession, spine surgery, allografts are frequently used for reconstructive procedures and to augment autogenous bone graft. To have this limited, for an indefinite study period, would compromise **the** care of many patients.

I strongly suggest that the safe use of allograft be continued now, as it has in the past, without further regulatory requirements.

Sincerely,



Michael R. Moore, M.D.
MRM:mm

97N 4845

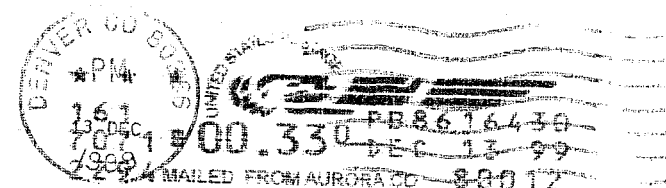
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